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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/646,748	00/00/00	BOZA	J 112701 036

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EXAMINER	
MOHAMED,A	
ART UNIT	PAPER NUMBER
1653	7

DATE MAILED: 07/03/01

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.	Applicant(s)
09/646,748	BOZA ET AL.
Examiner	**Art Unit**
ABDEL A. MOHAMED	1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jan 2, 2001*

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-10* is/are pending in the applica

4a) Of the above, claim(s) _____ is/are withdrawn from considera

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-10* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirem

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☒ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

ACKNOWLEDGMENT FOR PRIORITY, IDS, STATUS OF THE APPLICATION AND CLAIMS

1. This application is filed under 35 U.S.C. 371 on 9/12/00 having a filing date of 2/22/99 of PCT/EP99/01274. Acknowledgment is made of Applicant's claim for priority based on EP application number 98201016.7 having a filing date of 3/31/98. Receipt is acknowledged of papers submitted under 35 U.S.C. § 119, which papers have been placed of record in the file. Also, the Information Disclosure Statement (IDS) and Form PTO-1449 filed ½//01 are acknowledged and considered. Claims 1-10 are present for examination.

TITLE OF THE INVENTION

2. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

ABSTRACT MISSING

3. This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

OBJECTIONS TO TRADEMARKS AND THEIR USE

4. The use of the trademarks or tradenames "Nutricomp®Immun", "Reconvan®", "Glutasorb®", "PEPAMEN®", "PROPEPTIDES®" and "ALFARE®" have been noted in this application. Further, some of the trademarks or tradenames have not been capitalized, they should be capitalized whenever they appear and be accompanied by the generic terminology. Although, the use of trademarks are permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in a manner which might adversely affect their validity as trademarks.

Further, the specification which specifies the generic terminology should include published product information sufficient to show that the generic terminology or the generic description are inherent in the article referred by the trademarks. These description requirement are made because the nature and composition of articles denoted by trademarks can change and affect the adequacy of the disclosure.

OBJECTION TO IMPROPER MULTIPLE DEPENDENT CLAIMS

5. Claims 8-10 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only and/or cannot depend from any other multiple dependent claims. See MPEP § 608.01(n). However, the claims have been treated on the merits.

CLAIM REJECTIONS-35 U.S.C. § 101, NON-STATUTORY

6. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-10 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki,* 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner,* 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

CLAIM REJECTIONS-35 U.S.C. § 112^{2nd} PARAGRAPH

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-10 provide for the use of whey protein, or a protein mixture as a protein source of an enterally administrable nutritional composition fro increasing plasma glutamine concentration in a stressed mammal or for increasing muscle glutamine concentration in a mammal or for use as nutritional/therapeutic composition to a mammal suffering from injured, diseases or

under-developed intestines, but, since the claims do not set forth any steps involved the method/process, it is unclear what method/process Applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 1-3 are indefinite in the recitation "a protein mixture which....." because it is not clear to what kind of protein mixture the claims are referring. Appropriate clarification is required.

The syntax of claim 7 is unclear and indefinite in the recitation "...having a molecular weight of less than 1000Da.....", ".....having a molecular weight of 1000 Da to 5000 Da....." and ".....having a molecular weight of greater than 5000 Da" because the claim recites three different ranges in one claim. If Applicant intends to claim the preferred range as well as the broad range, then, the Office recommends the use of three dependent claims claiming the recited ranges. Also, the claim is indefinite and confusing in the recitation "less than ....." and "greater than...." because it is unclear as to the lower range/limitation by the recitation "less than" since the lower limitation/range could be from zero to recited maximum range/limitation. Similarly, the recitation of "greater than...." makes the claim indefinite because it is unclear as to higher range/limitation since the higher range/limitation could be from the recited range/limitation up to infinity. Thus, amendment of the claim to recite definite range/limitation is suggested.

CLAIM REJECTIONS-35 U.S.C. § 102(b)

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Maubois et al. (U.S. 4,427,658).

Claims 1-10 are directed to methods for providing glutamine by using whey protein (hydrolyzed) or a protein mixture enterally administered to a patient to increase plasma glutamine concentration in stressed mammal (claim 1), to increase muscle glutamine concentration in mammal (claim 2), to use as nutritional/therapeutic composition to a mammal suffering from injured, diseased or under-developed intestines (claim 3) and to provide energy of the nutritional composition thereof (claims 8-10).

Maubois et al. disclose a hydrolysate from whey protein for human nutrition applicable in intensive care unit as metabolic therapy according to the requirement of the patient (See e.g., col. 3, lines 33-41). Any type of whey can be used as starting material in addition to glutamic acid, arginine, lysine and tyrosine; and the soluble whey proteins may have molecular weights between 500 and 50, 000 Daltons (See e.g., col. 4, lines 37 to 53 and col. 7, lines 64-66). The product (hydrolysate) is used in therapeutic nutrition or as an intensive care medicine, as a medicament for treatment of digestive disorders of resected intestines or digestive infections such as for example

gastritis, septic ulcers, ileitis, insected intestines and colitis. Hence, clearly teaching as a medicament of patient, (being stressed mammals) with gastro-duodenal ulcers, partly removed intestines or ileitis (See e.g., col. 11, lines 43 to col. 12, lines 8, Examples 2-3 and 5-6). Thus, as the whey protein hydrolysate comprises glutamine and it is used fro nutritional purposes, it increases plasma glutamine concentration in mammals, increases muscle glutamine concentration in mammals, and provides treatment to patients with gastro-duodenical ulcers, partly removed intestines as ileitis being mammals suffering from injured, diseased or underdeveloped intestines.

With respect to the use of whey protein or protein mixture as a protein source alone or further including a lipid source or a carbohydrate source as claimed in claims 8-10, respectively to provide energy of the nutritional composition; this functional limitation (i.e., to provide energy of the nutritional composition) is considered inherent in the composition product which includes whey protein, or a protein mixture. Further, since energy and its use or effect are not defined in the specification and independent claims 1-3, the prior art clearly anticipates the claims because it discloses a high energy source of nutritional composition intended to increase the glutamine concentrations in plasma and muscle of a mammal, and in patients suffering from gastro-intestinal diseases/infections. Thus, in the absence of evidence to the contrary, the nutritional formulation disclosed by the reference anticipates claims 1-10 as drafted.

9. Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Rooyackers et al. (Clinical Nutrition, Vol. 14, No. 2, pp. 105-115, 1995).

Claims 1-10 are directed to methods for providing glutamine by using whey protein (hydrolyzed) or a protein mixture enterally administered to a patient to increase plasma glutamine concentration in stressed mammal (claim 1), to increase muscle glutamine concentration in mammal (claim 2), to use as nutritional/therapeutic composition to a mammal suffering from injured, diseased or under-developed intestines (claim 3) and to provide energy of the nutritional composition thereof (claims 8-10).

Rooyackers et al. disclose a nutritional composition comprising a glutamine-rich protein source having a wheat protein hydrolysate and whey protein hydrolysate mixtures administered enterally in which the protein source increased the two main glutamine pools i.e., plasma and muscle (See e.g., abstract, pages 105, 107 and 111, experiments 1-2 and Table 4). On page 113, right column, last paragraph and page 114, the reference teaches that the use of glutamine-rich protein as nutritional composition has improved small intestine integrity and morphology in both catabolic animal models and post operative patients. Thus, clearly showing that the nutritional composition provides glutamine to a mammal suffering from injured or diseased intestine.

In regard to the molecular weight of claim 7, the molecular weight is not disclosed in the prior art; however, the claim as drafted recites any hydrolysate whey protein having a molecular weight which is less than 1,000 Da or having a molecular weight of 1,000 Da to 5,000 Da or a molecular weight greater than 5,000 Da; and does not define the molecular wight as functional

limitation, rather, the claim defines the molecular weight as properties of the hydrolysate whey protein formulation. Thus, it is the Examiner's position that the hydrolysate whey protein formulations of the prior art would have the same molecular weight as claimed (i.e., less than 1,000 Da or greater than 5,000 Da) because the claim does not identify specific protein(s) having a molecular weight greater than 5,000 Da, or fragments thereof having a molecular weight less than 1,000 Da, and as such, the molecular weight is an inherent properties of the prior art protein.

With respect to the use of whey protein or protein mixture as a protein source alone or further including a lipid source or a carbohydrate source as claimed in claims 8-10, respectively to provide energy of the nutritional composition; this functional limitation (i.e., to provide energy of the nutritional composition) is considered inherent in the composition product which includes whey protein, or a protein mixture. Further, since energy and its use or effect are not defined in the specification and independent claims 1-3, the prior art clearly anticipates the claims because it discloses a high energy source of nutritional composition intended to increase the glutamine concentrations in plasma and muscle of a mammal, and in patients suffering from gastro-intestinal diseases/infections. Thus, in the absence of evidence to the contrary, the nutritional formulation disclosed by the reference anticipates claims 1-10 as drafted.

CITATION OF RELEVANT PRIOR ART

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

A. Boza et al. (Eur.J. Nutr., Vol. 39, No. 5, pp. 237-243, 2000) teach the use of protein hydrolysate vs free amino acid-based diets in which the diets containing peptides were more effective than diets containing free amino acids in the nutritional recovery of the starved rat.

B. Boza et al. (Clinical Nutrition, Vol. 19, No. 5, pp. 319-325, October 2000) describe data suggesting that glutamine supplementation of the diet does not increase plasma and tissue glutamine concentration in healthy growing rats, while the addition of arginine to the diet decreases glutamine body stores.

C. Schmidl et al. (U.S. Patent No. 5,719,134) disclose the use of a dietary composition comprising a mixture of carbohydrate, lipid and protein as nutrition to humans.

D. Miller et al. (U.S. Patent No. 6,019,999) describe a mixture of liposome and whey protein product thereof for use as a sports nutrition supplement and fro use in medical or clinical catabolic applications.

E. Portman (U.S. Patent No. 6,051,236) discloses a nutritional composition for optimizing muscle performance during exercise and fro enhancing muscle cell repair and recovery following the cessation of exercise.

CONCLUSION AND FUTURE CORRESPONDENCE

11. No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (703) 308-3966. The examiner can normally be reached on Monday through Friday from 7:30 a.m. to 5:00 p.m. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (703) 308-2923. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Christopher S. F. Low

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